

March 14, 2002

Aegis Pharmaceuticals, Inc.  
Attention: Agnes Varis  
U.S. Agent for Egis Pharmaceuticals, Ltd.  
96 Route 23  
Little Falls, NJ 07424

Dear Madam:

This is in reference to your abbreviated new drug application dated April 21, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Buspirone Hydrochloride Tablets USP, 5 mg and 10 mg.

Reference is also made to the tentative approval letters issued by this office on November 16, 1998 and July 27, 2000, and to your amendments dated August 6, and September 13, 2001; February 21 (2 amendments), February 25, February 27, and February 28, 2002.

The listed drug product (RLD) referenced in your application, BuSpar Tablets of Bristol Myers Squibb Company Pharmaceutical Research Institute (Bristol Myers Squibb), is subject to a period of patent protection which will expire on November 14, 2008 (U.S. Patent No. 5,015,646 (the '646 patent)). Your application contains a patent certification to this patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on the '646 patent. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless an action is brought for infringement of the '646 patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified FDA that Egis Pharmaceuticals, Ltd. (Egis) has complied with the requirements of Section 505(j)(2)(B) of the Act, and that no action for patent infringement against the '646 patent was brought against Egis within the statutory forty-five day period.

We also note that Bristol Myers Squibb, holder of the NDA for BuSpar Tablets, has informed the agency that it will not enforce its exclusivity rights to pediatric use information against ANDA applicants that seek to include such information in their labeling for this drug product.

Furthermore, the agency's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations", (the "Orange Book"), reveals that 180-day generic drug exclusivity previously granted to Danbury Pharmacal, Inc. for the 5 mg and 10 mg strengths of the drug expired on September 26, 2001.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Buspirone Hydrochloride Tablets USP, 5 mg, and 10 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (BuSpar<sup>®</sup> Tablets, 5 mg, and 10 mg, respectively, of Bristol Myers Squibb Company Pharmaceutical Research Institute). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research